REMARKS

Applicant has carefully reviewed the Office Action mailed September 19, 2008 and offers the following remarks.

Status of the Claims

Claims 1, 5, 7, 9, 11-15, 17-20, 22, 24, and 26-45 are pending in the present application.

Claims 2-4, 6, 8, 10, 16, 21, 23, and 25 were previously cancelled.

Claims 26-45 were previously withdrawn.

Rejection Under 35 U.S.C. § 112

Claims 1, 5, 7, 9, 11-15, 17-20, 22, and 24 were rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. In particular, the Patent Office alleges that the claim language regarding instructing the human subject via the first and second feedback signal is not described in the Specification because the Specification "only has the feedback signal providing and (sic) indication to the patient and instruction further provided for the patient by a person instructing the patient." (Office Action mailed September 19, 2008, p. 2). Applicant respectfully traverses.

Notably, 35 U.S.C. § 112 does not require that the claimed invention subject matter be described literally, i.e., using the same terms, in order for the disclosure to satisfy the description requirement. MPEP § 2106. All that is required is that the claim limitations be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163. Applicant refers to paragraphs 0007, 0010, 0019, 0021, 0022, and 0025-0037 of the Specification as published in U.S. Patent Application Publication No. 2005/0096555.

Applicant asserts that these paragraphs, despite not using the exact words, when read in conjunction with the entire Specification, disclose and support the claimed step of "instructing the human subject, via the second biofeedback signal, an exact moment to begin inhalation and instructing the human subject, via the first biofeedback signal, an exact moment to begin exhalation, such that the human subject aligns their breathing with the natural heart rate to attempt to achieve consistency in the natural heart rate, wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type."

In particular, paragraph 0007 states in part:

The most direct and effective manner of achieving this alignment is for the human subject to consciously align them via biofeedback, i.e., present the human subject **with a biofeedback signal that indicates exactly when to inhale and exactly when to exhale such that the breathing cycle achieves exacting alignment with the natural heart rate variability cycle**.

Likewise, paragraph 0010 states:

Because the heart rate variability signal of the untrained subject is typically highly erratic and synchrony of said signal may be difficult to detect, a specific **instructive** method employing other biofeedback devices and methods is specified. Via the application of this **instructive** method, the human subject is **led to** achieve a detectable level of synchrony of their heart rate variability signal.

Paragraph 0019 reads in part:

This is accomplished by providing a biofeedback signal in the form of an audible, visual, or sensory stimulus, **to indicate when the subject should begin inhalation and a second signal to indicate when the subject should begin exhalation.** These signals are unique so the subject is able to clearly distinguish the beginning of inhalation from the beginning of exhalation.

Paragraph 0025 discloses that "**via biofeedback, the human subject is trained** to identify the subjective state and associated sensation that relates to maximal alignment."

In light of the above description in the Specification, and reading the Specification as a whole, Applicant respectfully submits that the instructing via feedback signals step of the claims is either expressly or implicitly supported by the written description contained in the Specification. Applicant therefore respectfully submits that one of ordinary skill in the art would recognize that the application had possession of the invention as claimed at the time that the application was filed. The rejection under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement should be withdrawn.

Background

By way of background, Applicant refers to paragraph 0007 of the Specification:

"As previously described, a relationship exists between the heartbeat rate specified in terms of heart rate variability, and the breathing cycle. While the heart has its own tendency toward a natural variable rhythm, there is a strong correlation with breathing according to this specific relationship: as inhalation occurs, there is a tendency for the heartbeat rate to increase, as exhalation occurs,

there is a tendency for the heartbeat rate to decrease. It is important to note that the relationship between the natural heart rate variability cycle and the breathing cycle is indirect. This is to say that while the heart rate variability cycle/breathing cycle relationship exists, in untrained subjects, their alignment appears highly random. Consequently, these same subjects exhibit a highly incoherent heart rate variability pattern. As previously stated, maximal coherence of the heart rate variability is achieved when the cycle of breathing is synchronized with the natural heart variability cycle in time and amplitude."

In addition, in the present application, the heart rate variability cycle (the periodicity of increasing and decreasing heart rate) and the breathing cycle (the periodicity of inhalation and exhalation) are considered to be two independent cycles (Specification, paragraph 0008).

The present application discloses achieving synchrony of the breathing cycle with the heart rhythm by monitoring the heart rate and consciously synchronizing the breathing cycle with the heart rhythm. The goal of the claimed invention is to achieve synchrony of the breathing cycle with the heart rhythm based on the natural heart rate of the human subject, not to synchronize the heart rhythm with the breathing cycle, as is done in Vaschillo and Stabler. This represents a fundamental scientific distinction between Applicant's invention and Vaschillo and Stabler. Vaschillo and Stabler both attempt to assess and determine a given user's ideal breathing frequency, then have the user breathe at that frequency in order to realize health benefit. The intent of the claimed invention is to have the human subject breathe directly in synchrony with their natural heart rhythm. Therefore, in the case of the claimed invention, the subject's heart rate itself serves as a breathing "reference rhythm." Scientifically, this is a fundamentally different method employing a different psychophysiological mechanism than the method employed by Vaschillo and Stabler. It can be seen that both the goals and the methods of Vaschillo and Stabler are different from the goal and method of the claimed invention, so it is not surprising that neither Vaschillo nor Stabler teaches or suggests each and every element of the claimed invention.

Rejection under 35 U.S.C. § 102(b) – Vaschillo et al.

Claims 1, 5, 7, 9, 11-15, 17-20, 22, and 24 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,997,482 to Vaschillo et al. (hereinafter "Vaschillo"). For the Patent Office to prove anticipation, each and every element of the claims must be present in

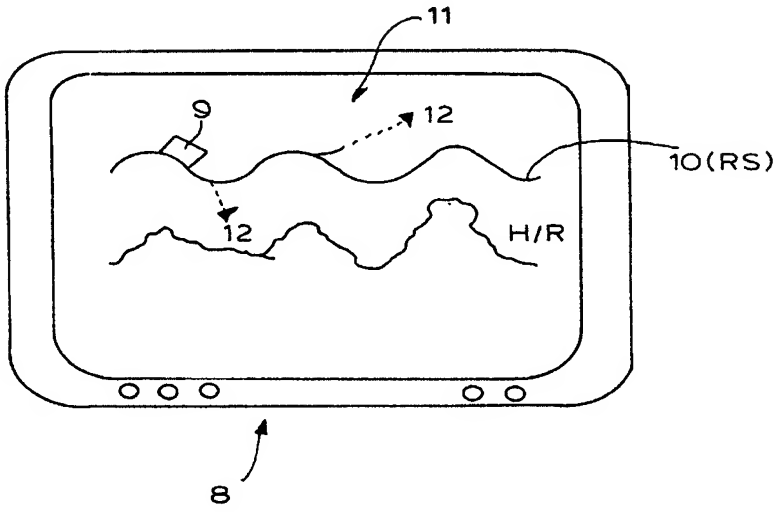
the reference. Furthermore, the elements of the reference must be arranged as claimed. MPEP § 2131.

Claim 1 provides that the human subject is instructed on the moment to breathe such that the human subject aligns their breathing with the natural heart rate to attempt to achieve consistency in the natural heart rate. Greater consistency results in a more coherent heart rate variability (HRV). Greater consistency in a human subject's natural heart rate can be achieved by a human subject aligning their breathing cycle with their natural heart rate cycle. The claimed invention provides this breathing instruction to the human subject such that the human subject aligns his breathing cycle to his natural heart rate cycle. The human subject breathes in response to the instruction to align his breathing cycle with his natural heart rate cycle. This is in response to the inventor's recognition that a human subject's breathing cycle influences a human subject's heart beat rate cycle.

In contrast to the claimed invention, which achieves synchrony of the breathing cycle with the heart rhythm by monitoring the heart rate and consciously synchronizing the breathing cycle with the heart rhythm, Vaschillo achieves synchrony of the heart rhythm with the breathing cycle by having the user breathe at a variable reference rhythm, then adjusting that rhythm until the heart rhythm aligns with the reference rhythm. Vaschillo therefore has the user breathe at a reference rhythm, rather than at a first and second biofeedback signal that indicates that the natural heart rate of the human subject has reached the maximum and minimum heart rate. Vaschillo therefore does not teach or suggest that the human subject "align their breathing with the **natural heart rate** to attempt to achieve consistency in the natural heart rate," as recited in claim 1.

Vaschillo does not instruct a human subject to breathe based on their natural heart rate cycle, as provided in the claimed invention. Instead, as illustrated in Figure 2 below, Vaschillo instructs the user to breathe in accordance with a predetermined reference signal (RS) (Vaschillo, col. 6, lines. 52-55). The reference signal (RS) is not a biofeedback of the user's heartbeat rate, but is instead a predetermined signal at one possible breathing cycle frequency (Vaschillo, col. 6, lines 52-55). The user is instructed to breathe according to the reference signal (RS) on a display (8). The user is informed whether their breathing is in accordance with the reference signal (RS) (H/R signal in Figure 2). Vaschillo then records the user's heartbeat cycle that results from the user breathing at the reference signal (RS) frequency.

FIG. 2



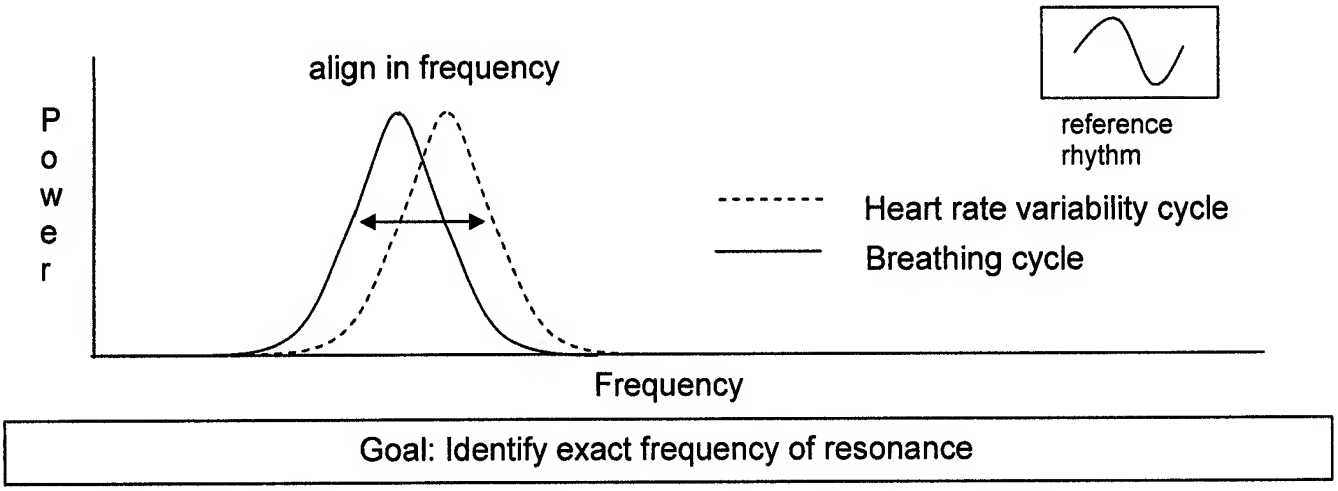
Vaschillo repeats these steps over a series of varied reference signal (RS) frequencies in a sweeping fashion. This data is then analyzed to determine at which reference signal (RS) frequency the user's breathing aligns (i.e., resonates) with his heartbeat cycle. Phase shift differences between the reference signal (RS) frequency and the user's heart rate are analyzed in the frequency domain to determine resonance, or lack therof. Zero phase shift represents resonance. Figures 4A-4B of Vaschillo illustrate this data recordation and analysis.

Thus, Vaschillo instructs the user to breathe based on a variety of reference signals (RS) and not any biofeedback signal. Vaschillo is just a monitoring system that does nothing to instruct the user on how to align his breathing with his natural heart rate. Vaschillo's goal is to simply monitor and determine the current state of the user's heart rate cycle (i.e., the resonance frequency). No instructions are provided to the user to breathe according to his own natural heart rate or any other biofeedback.

On the contrary, the claimed invention is not a tool to quantify resonance based on theoretical breathing reference signals like in Vaschillo. The claimed invention instructs the human subject on the actual breathing cycle such that the human subject breathes to align his breathing cycle to his natural heart rate cycle to attempt to achieve coherence. The claimed invention provides an instruction signal based on actual biofeedback from the human subject's heartbeat cycle. Vaschillo does not. Vaschillo is designed to analyze the current state of the user's heartbeat. The claimed invention is designed to instruct and have the human subject

breathe to achieve coherence regardless of the current state of the human subject's heartbeat. Vaschillo analyzes, whereas the claimed invention instructs and achieves.

A further, but related distinction lies in the fact that Vaschillo performs its analysis in the frequency domain. The claimed invention is not analyzing data in the frequency domain and has no need to do so, because the claimed invention is not analyzing at what breathing frequency the uers's heartbeat is resonant. The claimed invention is instructing the human subject on how to breathe to reach coherence regardless of the current state of the human subject's heartbeat. This distinction is illustrated in the drawing below. This drawing represents Vaschillo's operation, wherein a phase difference is measured between the user's heartbeat and his breathing cycle to determine resonance, or lack thereof.



From the above, it is seen that Vaschillo has the user breathe at some "target" frequency during the assessment activity and at some later time. In the case of Vaschillo, this "target" frequency is achieved by having the user breathe at a rhythm at which the heart synchronizes with the breathing cycle. Breathing at the target frequency of the reference signal in Vaschillo is one means of achieving synchrony between breathing and heart rhythms, but it is not the method as claimed in claim 1, which uses the natural heart rate of the human subject.

Moreover, Vaschillo does not teach or suggest "wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type." Vaschillo does not disclose two different feedback types to provide the instructions to the human

subject to begin inhalation and exhalation. Thus, Vaschillo does not teach this element of claim 1. Accordingly, Vaschillo does not teach each and every element of claim 1 for this additional reason.

For the above reasons, Applicant respectfully submits that Vaschillo does not anticipate claim 1. Claims 5, 7, 9, 11-15, 17-20, 22, and 24 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, 22, and 24 should be withdrawn for at least the same reasons.

Rejection under 35 U.S.C. § 103(a) – Stabler et al.

Claims 1, 5, 7, 9, 11-15, 17-20, and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,836,681 B2 to Stabler et al. (hereinafter "Stabler"). Applicant respectfully traverses. For the Patent Office to establish *prima facie* obviousness, the Patent Office must show where each and every claim element can be found in the reference. MPEP § 2143.03.

In contrast to the claimed invention, which achieving synchrony of the breathing cycle with the heart rhythm by monitoring the heart rate and consciously synchronizing the breathing cycle with the heart rhythm, Stabler, like Vaschillo, achieves synchrony of the heart rhythm with the breathing cycle by having the user breathe at a variable reference rhythm.

Like Vaschillo, Stabler has the user breathe with a reference rhythm in such a way as to achieve "the zone" (Stabler, Figure 1). Stabler defines the zone as a frequency range wherein the spectral power of the heart rate should be maximized. It can be assumed that Stabler's "zone" is indicative that the heart rhythm is nearing alignment with the breathing cycle. Stabler acknowledges that when performed correctly, the user's heart rate can be seen to "follow the breathing cycle" (Stabler, column 3, paragraph 7).

Stabler does not instruct a human subject to have them breathe at a target rate based on the user's heart rate cycle (Stabler, col. 2, lines 35-38). Instead, Stabler simply displays a graph of heart rate variability and amplitude of breathing results to the user. The graph only indicates to the user that they are in "the zone," which Stabler makes clear is relative to the amplitude of the HRV cycle. Stabler does not teach or suggest that these results provide instructions to the user to breathe such that the user aligns his breathing cycle with his heart rate cycle. Nor does the user in Stabler breathe according to the results provided on the display. The user is simply

given the results to indicate if the user is in the "zone" without any real understanding of the relationship of inhalations and exhalations to transitions in the natural heart beat rate cycle (Stabler, col. 4, lines 1-17). Stabler simply requires the user to continue breathing in a controlled fashion until the user gets it right and reaches the "zone."

When the user is "in the zone," the heart rhythm will follow the breathing cycle. In Stabler, when the user is performing correctly, it should be seen that the heart rate is following the respiration (Stabler, column 3, lines 53-64). Stabler's "zone" is also a broad indication of synchrony of the heart rhythm with the breathing cycle. Like Vaschillo, Stabler leads the heart rhythm to synchronize with the breathing cycle by having the user breathe at a rhythm at which the heart rhythm synchronizes with the breathing cycle.

However, this is fundamentally different than the claimed invention, which synchronizes the breathing cycle with the natural heart rate of the human subject by providing indications to inhale and exhale in synchrony with biofeedback signals derived from the human subject's natural heart rate. The key recognition of inhalation and exhalation in the breathing cycle to achieve coherence, as well as instructing the human subject specifically at the transition times as to when to inhale and exhale based on the human subject's natural heart rate, as set forth in the claimed invention, is not present in Stabler. Thus, Stabler does not render the claimed invention obvious, and thus this rejection must be withdrawn.

In addition, Stabler does not teach or suggest "wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type." Stabler does not disclose two different feedback types to provide the instructions to the human subject to begin inhalation and exhalation. Thus, Stabler does not teach this element of claim 1. Accordingly, Stabler does not teach each and every element of claim 1 for this additional reason.

Claims 5, 7, 9, 11-15, 17-20, and 22 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, and 22 should be withdrawn for at least the same reasons as claim 1. Applicant respectfully submits that claims 1, 5, 7, 9, 11-15, 17-20, and 22 are in condition for allowance and notice of the same is requested at the earliest possible date.

Summary

Claim 1 recites "instructing the human subject, **via the second biofeedback signal, an exact moment to begin inhalation and instructing the human subject, via the first biofeedback signal, an exact moment to begin exhalation**, such that the human subject **aligns their breathing with the natural heart rate** to attempt to achieve consistency in the natural heart rate, wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type." The first and second biofeedback signals used to align the human subject's breathing with the natural heart rate of the human subject are provided to the human subject to indicate that the natural heart rate of the human subject has reached a minimum and a maximum heart rate. Thus, in claim 1, the human subject's natural heart rate is used to guide the human subject's breathing cycle such that it is aligned with the human subject's natural heart rate. The natural heart rate of the human subject is monitored, and biofeedback signals at the minimum and maximum are generated and provided to the human subject such that the human subject is instructed to inhale and exhale in accordance with the biofeedback signals.

In contrast, Vaschillo presents a breathing reference rhythm to the user and instructs the user to breathe at the reference rhythm. This reference rhythm is completely external to, and unrelated to, the human subject's actual heart rate. Likewise, Stabler presents a breathing reference rhythm to which the user synchronizes their breathing cycle. This rhythm is also completely external and unrelated to the human subject's actual heart rhythm. Thus, Vaschillo and Stabler do not use the human subject's natural heart rhythm to align the breathing cycle, as in done in the claimed invention. Instead, in both Vaschillo and Stabler, the user's respiration is monitored because Vaschillo and Stabler are trying to achieve synchronization of the heart rhythm with the breathing cycle; thus, Vaschillo and Stabler need to monitor the user's respiration. The claimed invention does not need to monitor respiration because the human subject is governing his own respiration by inhaling and exhaling as instructed by the biofeedback signals representing the minimum and maximum of their natural heart rate. This is another fundamental difference between the Vaschillo and Stabler and the claimed invention.

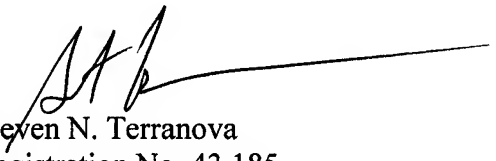
For the above reasons, neither Vaschillo nor Stabler teaches or suggests each and every element of the claimed invention. Thus, the claimed invention is patentable over both Vaschillo and Stabler.

Conclusion

The present application is now in condition for allowance and such action is respectfully requested. The Examiner is encouraged to contact Applicant's representative regarding any remaining issues in an effort to expedite allowance and issuance of the present application.

Respectfully submitted,

WITHROW & TERRANOVA, P.L.L.C.

By: 

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